REMARKS

Reconsideration of this application, as amended, is respectfully requested.

The Examiner objects to Claims 1-9 and 15-22 due to informalities in reciting acronyms such as "SHS," "TRT" and "TRTV." To comply with the Examiner's requirement for correction and render this objection moot, the claims have been rewritten to recite the full name.

The Examiner rejects Claims 1-9, 13, 14 and 18 under 35 U.S.C. § 112, second paragraph, for reasons set forth on pages 2 and 3 of the Office action. Without comment as to the merits of this rejection but to advance prosecution towards an early allowance, the claims have been rewritten for the better readability thereof.

It is noted that Claim 18 as originally filed was dependent upon Claim 17, and not Claim 1 per the Office action on page 3. Nevertheless, the claim has been revised in order for the term "said post-*in ovo*" to read better. As the Examiner will further notice, other minor corrections have also been made in the claims to expedite matters such as, for example, Claim 21 is now dependent upon Claim 20 instead of Claim 21, which was an obvious mistake.

Since the present amendment obviates the rejection, Applicant respectfully requests that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

The Examiner rejects Claims 10-14 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement for reasons set forth on pages 3 and 4 of the Office action. Without comment as to merits of the rejection but to advance prosecution towards an early allowance, Claims 10 and 12 have been amended for the better readability thereof. Claim 10 now recites a process for protecting turkeys or chickens against infection from exposure to virulent strains of turkey rhinotracheitis virus ("TRTV"). Similarly, Claim 12 now recites an *in ovo* vaccine for protecting turkeys or chickens against infection from exposure to virulent TRTV. The specification makes it quite clear that the present invention relates to the method and the *in ovo* vaccine for protecting the avian host against upper respiratory tract infections due to exposure to virulent TRTV, certainly not protecting the avian host against exposure to the virus as the original claim language had inadvertently implied. To provide Applicant's true intent in no uncertain terms, the present amendment conforms the claim language of Claims 10 and 12 to the teachings in the specification. In view of the amendment, it is respectfully asked that this enablement rejection be withdrawn.

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The Examiner rejects Claims 19-21 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement for reasons set forth on page 4 of the Office action. Without comment as to merits of the rejection but to advance prosecution towards an early allowance, the claims have been amended to include the dosage range of at least about $10^{3.2}$ $TCID_{50}$ per egg to about $10^{5.5}$ $TCID_{50}$ per egg in accordance with the working examples involving *in ovo* administration to turkeys showing safety and efficacy at the amount of $10^{5.5}$ $TCID_{50}$ per egg (see pages 4-9 of the specification). One of ordinary skill in the art would readily appreciate that the originally recited range encompasses the experimental data for chickens in working Example 4. The range is even greater for turkeys, large chickens and other large birds. As taught by the specification, the 50% tissue culture infectious dose ($TCID_{50}$) will vary depending upon the avian species being immunized and its body size. For example, smaller birds require smaller dosages (see the discussion on page 3, lines 17-28 of the specification).

Desirably, the *in ovo* vaccine and method of administration will result in substantially no decrease in the percentage of eggs that hatch after *in ovo* vaccination when compared to a substantially identical control (see the specification on page 4, lines 8-17 thereof). Preferably, the decrease is less than about 10%; more preferably, less than about 5%; and even more desirably, less than about 1%. The maintenance of a relatively normal rate of hatchability demonstrates that the vaccine is safe for *in ovo* administration to the avian host. It is well within the skill of the ordinary practitioner to be able to titrate the actual dose per egg and then determine the hatchability at each dosage concentration through routine testing. Thus, one of ordinary skill in the art would be able to practice the claimed invention without undue experimentation.

In view of the amendment and the foregoing comments, it is respectfully requested that the Examiner withdraw the rejection of Claims 19-21 under 35 U.S.C. § 112, first paragraph.

The Examiner rejects Claims 1, 3-9, 15, 17 and 18 under 35 U.S.C. § 102 (b) as allegedly being anticipated by Poston *et al.* (WO 99/53950) for reasons set forth on pages 5 and 6 of the Office action. Applicant respectfully traverses the rejection for the following reasons.

To find anticipation of the claims, there must be an identity of invention between Applicant's invention and the teachings of Poston *et al.* In other words, Poston *et al.* do not anticipate the rejected claims if the claimed invention is not the same as the invention described in the reference. By comparing the present invention with the description in the cited reference, it is clear that the

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present invention is not described by the reference. In point of fact, there are patentable differences over the art.

Specifically, Poston *et al.* require the critical presence and *in ovo* administration of interferon in each and every instance. The Abstract, the Detailed Description of the Invention, the Examples and the claims include interferon in conjunction with the live, pathogenic viruses. There is absolutely no description of a method of protecting an avian host against Newcastle Disease (ND) by administering an *in ovo* composition comprising a live, attenuated ND virus in the absence of interferon, let alone the live, attenuated TRT virus of the present invention.

In view of the foregoing remarks and the lack of identity of invention, it is demonstrated that Poston *et al.* do not anticipate the claimed invention. As a result, Applicant respectfully asks that the rejection of Claims 1, 3-9, 15, 17 and 18 under 35 U.S.C. § 102 (b) be withdrawn.

The Examiner rejects Claim 16 under 35 U.S.C. § 102 (b) as allegedly being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as allegedly obvious over Poston *et al.* for reasons set forth on pages 6 and 7 of the Office action. Applicant respectfully traverses the rejection for the following reasons.

For the same reasons as applied to the rejection of Claims 1, 3-9, 15, 17 and 18, Poston *et al.* do not anticipate Claim 16. Interferon, which is described as an essential component of the method and pharmaceutical composition of the cited reference, is missing from Applicant's dependent Claim 16 and base Claim 15. There is no identity of invention.

In terms of the obviousness rejection, the cited reference also fails to suggest the claimed invention. Basically, Claim 16 is drawn to a safe and efficacious method for inoculating poultry against TRT disease that comprises the *in ovo* administration of an immunologically effective amount of a live, attenuated strain of TRT virus, a pharmaceutically acceptable carrier and an ND or infectious bursal disease vaccine. In sharp contrast, Poston *et al.* require the critical addition of interferon to all forms or administration of their *in ovo* vaccine and do not teach or imply that this crucial ingredient can be omitted from the *in ovo* vaccine without significant, adverse effect.

If anything, the reference actually teaches away from administering a live pathogenic virus in the absence of interferon. Poston *et al.* state that *in ovo* live Newcastle Disease virus (NDV) vaccination is usually toxic to the embryo, and birds that do hatch from *in ovo* vaccinated eggs exhibit high early mortality (sentence bridging pages 1 and 2). To decrease the pathogenicity of the

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NDV vaccine, Poston *et al.* expressly teach that interferon must be administered with the NDV vaccine. Since the interferon allows the production of a protective immune response in the avian subject, the reference further describes a method that permits a lower, effective dosage of the live pathogenic virus in combination with interferon. It is important to note, therefore, that every embodiment of the invention of Poston *et al.* described in the Abstract, the Detailed Description of the Invention, the Examples and the claims include interferon in conjunction with the live, pathogenic viruses. Poston *et al.* neither teach nor imply that interferon is optional or can be omitted from the *in ovo* method of administration without negative consequences. One of ordinary skill in the art would simply not arrive at the claimed invention without inventive effort.

In view of the foregoing remarks, it is clear to see that Poston *et al.* do not anticipate the claimed invention or render the claimed invention obvious. Consequently, Applicant respectfully asks that the rejection of Claim 16 under 35 U.S.C. § 102 (b) and 35 U.S.C. § 103(a) be withdrawn.

The Examiner rejects Claims 2 and 22 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Poston *et al.* as applied to Claims 1, 3-9, 15, 17 and 18, above, and further in view of Ricks *et al.* (Advances in Veterinary Medicine, 1999, 41:495-515) for reasons set forth on page 7 of the Office action. Applicant respectfully traverses the rejection for the following reasons.

It is submitted that the combined art of Poston *et al.* and Ricks *et al.* do not render Claims 2 and 22 obvious. The teachings of Ricks *et al.* only provide background information for the present invention in illustrating the general art-recognized techniques of *in ovo* administration. This secondary reference merely summarizes the state of the art with respect to the known use of the *in ovo* vaccination for prevention of Marek's disease, Newcastle disease, infectious bronchitis and infectious bursal disease. However, it does not recommend a broad application of the *in ovo* administration for other pathogenic viruses. To the contrary, Ricks *et al.* indicate that the injection of many posthatch vaccines *in ovo* is unsafe for the embryo and instruct that only those vaccines that are approved by APHIS for use *in ovo* should be used in the United States (see paragraph in middle of page 503).

Together, the combined references do not suggest the invention of Claims 2 and 22 for the main reason that neither reference imply that the *in ovo* method of administration can be used with a broad range of pathogenic viruses in the absence of interferon. There is no suggestion or expectation that interferon can be omitted from the vaccine of Poston *et al.* without significant loss of safety and

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efficacy when vaccinating a fragile, fertile egg with a pathogenic virus. The ordinary practitioner would have no reasonable expectation of success. In fact, the opposite is true. Based on the combined teachings of Poston *et al.* and Ricks *et al.*, the practitioner would expect a reasonable likelihood that the TRTV of the present claims would be harmful to the embryo and that the TRTV would fail to protect the avian host from TRT disease at any concentration. As such, the practitioner would have no motivation to discover an immunogenically-effective amount in a suitable vehicle of approximately 0.05 to 0.1 ml per egg or to obtain elevated titers of TRTV.

Based on the combined references in light of contemporary knowledge about TRTV, one of ordinary skill in the art would not predict that the live, pathogenic TRTV could be safe or effective without the co-administration of interferon. Surprisingly, Applicant has been successful in the *in ovo* administration of a live pathogenic virus without a high incidence of embryo mortality. The attainment of safety and efficacy is totally unexpected in view of the teachings in the art. As a consequence, the claimed invention is not *prima facie* obvious in light of the cited art.

Since it is demonstrated that Poston *et al.* in view of Ricks *et al.* do not render the claimed invention obvious, Applicant respectfully asks that the rejection of Claims 2 and 22 under 35 U.S.C. § 103(a) be withdrawn.

Accordingly, this application is now in condition for an allowance and such favorable treatment is respectfully urged.

Respectfully submitted,
WYETH

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